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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,343	03/30/2004	Michael J. Vazquez	101765.00032	2695

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/812,343	Applicant(s) VAZQUEZ ET AL.	
	Examiner Susannah Chung	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/30&8/23/04, 6/2/</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 20-32 are pending in this application.

Information Disclosure Statement

Applicant's information disclosure statement (IDS), filed on 03/30/2004, 08/23/2004, and 06/02/2005 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Priority

This application is a divisional of U.S. App. No. 10/486,508, filed on 02/11/2004, resulting in U.S. Pat. No. 6,911,463, which is a 371 of PCT/US02/21316 filed on 08/06/2002, which claims the benefit of U.S. Provisional App. No. 60/312,135, filed on 08/14/2001.

Response to Election/Restrictions

Applicant's election *with traverse* of Group I, Claims 20-26 drawn to compounds and pharmaceutical compositions of the formula in Claim 20, in the reply filed on 10/27/2005 is acknowledged. Also, the election of species of compound 32, N-[2R-hydroxy-3-[[4-methoxyphenyl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2,6-dimethyl benzamide, in Table 21 on page 185 is acknowledged. Based upon the election, examiner will begin searching compounds of the formula of claim 20, wherein **A** and **R4** are substituted phenyl.

Maintained Election/Restrictions

Applicant's traversal is on the ground that (1) the entire scope of Claim 20 encompasses one "inventive concept" (see Applicant's Response, page 13 of 17, line 18-19) and as such, claims 20-26 should be examined without restriction among Markush group members (see

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Applicant's Response, page 14 of 17, lines 2-3), and (2) process claims 27-31 are to be rejoined upon the elected product claims being found allowable (see Applicant's Response, page 15 of 17, lines 22-23) have been considered.

Applicant's argument that the entire scope of Claim 20 does encompass one inventive concept has been considered and is not found persuasive. Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, *and* (2) share a substantial structural feature essential to that utility (see MPEP 803.02, ¶3, Rev. 3, August 2005). Claim 20 does share a common utility, but does not share a substantial structural feature because substituents A and R4 contain hetero groups that may change the substantial structural feature essential to the utility. Therefore, restriction and election of species was required at this point in examination. If the elected species is found allowable, Examiner will broaden the scope of search and examination.

Second, process claims 27-31 will be rejoined if the product claim is found allowable. Please see previous office action mailed out on 09/27/2005.

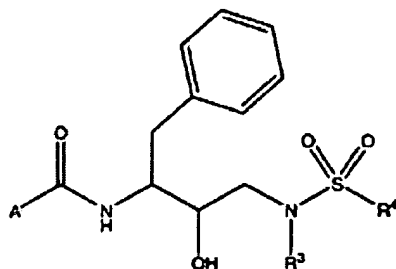
The requirement for restriction is required because unity of invention is lacking and the various classes and subclasses impose a serious burden on the Examiner to search and examine all of the above listed inventions.

Therefore, for the above reasons, the requirement is still deemed proper and is therefore made FINAL.

Scope of Elected Subject Matter

The scope of the invention of the elected subject matter is as follows: Claims 20-26 drawn to a retroviral protease inhibiting compound, represented by the formula,

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, wherein A and R⁴ are substituted phenyl, or a pharmaceutically acceptable salt thereof.

Based upon Applicant's election, Examiner will search various subclasses of classes 514 and 564. All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.)

Scope of Withdrawn Subject Matter

Claims 27-32 have been withdrawn from consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected subject matter. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 25 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 15 of U.S. Pat. No. 5,968,942, column 252, lines 59-61, Benzamide, N-[2R-hydroxy-3-[(4-methoxyphenyl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2,6-dimethyl.

Obviousness Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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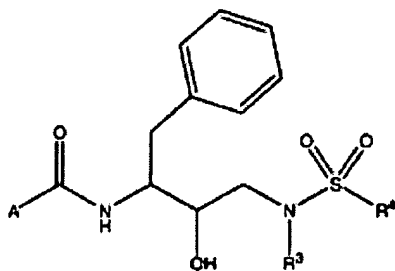
F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 12-16 of U.S. Patent No. 5,968,942 ('942 Patent).

Instant claims 20-26 disclose species of a compound of the formula,

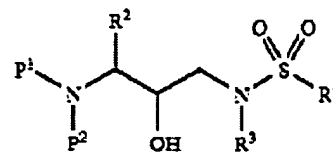


, its pharmaceutically acceptable salt thereof, wherein '942

Patent teaches this compound.

Determination of the scope and content of the prior art (MPEP § 2141.01)

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'942 Patent teaches a compound in claim 12 of the formula,

wherein **R4** is alkyl, haloalkyl, alkynyl, hydroxyalkyl, alkoxyalkyl, etc...; **R3** is hydrogen, alkyl, haloalkyl, alkynyl, hydroxyalkyl, alkoxyalkyl, etc...; **R2** is alkyl, aryl, cycloalkyl, cycloalkylalkyl or aralkyl; **P1** and **P2** independently represent hydrogen, alkoxycarbonyl, aralkoxycarbonyl, etc...

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between '942 Patent and the instantly claimed compounds is that the instant application gives more specific definitions than the '942 Patent compounds. Although the claims are not identical they are not patentably distinct from each other. For instance, **R2** in the instant application is alkyl, aryl, cycloalkyl, cycloalkylalkyl, or aralkyl, while in the instant application it is always aralkyl, i.e. phenylmethyl.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

Although the conflicting claims are not identical, they are not patentably distinct from each other because '942 Patent teaches the instantly elected compound, wherein **R4** is 4-methoxyphenyl; **R3** is 2-methylpropyl; **A** is 2,6-dimethylphenyl. In claim 15, column 252, lines 59-61, of '942 Patent, it teaches that the preferred species of Benzamide, N-[2R-hydroxy-3-[[4-methoxyphenyl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2,6-dimethyl, which is the elected species N-[2R-hydroxy-3-[[4-methoxyphenyl)sulfonyl](2-methylpropyl)amino]-1S-(phenylmethyl)propyl]-2,6-dimethyl benzamide.

Therefore, one skilled in the art would have found the variations in the compounds and compositions obvious when faced with the '942 Patent because both compounds are used for the same pharmacological use, i.e. as retroviral protease inhibitors, so one skilled in the art would expect similar properties and results.

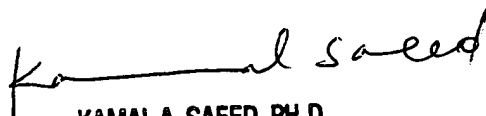
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
Patent Examiner, AU 1626


KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Date: 12/26/2005